



- x Germantown Emergency Center
- x Shady Grove Medical Center
- x White Oak Medical Center

Planned Deviation Documentation

Procedure:	D-Dimer																																																																											
Reason for Deviation:	<p>Shortage of Quality Control - D-Dimer testing volumes have exponentially increased due to COVID-19. The vendor has reported a shortage of D-Dimer Quality Control material.</p> <p>To decrease the amount of QC testing for D-Dimer, the QC setting on each Stago instrument has changed from QC being triggered to run every 4 hours to every 8 hours. (CAP requirement is every 8 hours with patient testing.)</p> <p>When QC is reconstituted, 500 uL aliquot will be removed, frozen, and labeled. 500uL will be loaded on the instrument in microcups.</p>																																																																											
Medical Director or Designee:	Dr. Cacciabeve / Rob SanLuis – <i>refer to electronic signatures</i>		Date:																																																																									
Supervisor:	Hollie Genser		Date: 2/18/21																																																																									
Deviation Start Date:	2/18/21		Deviation End Date: Revise SOP to match change																																																																									
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">Testing Personnel Signatures</th> <th style="width: 25%;">Start Deviation Signatures</th> <th style="width: 25%;">End Deviation Signatures</th> <th style="width: 25%;"></th> </tr> <tr> <th>Printed Name / Tech Code</th> <th>Signature</th> <th>Signature</th> <th>Date</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>					Testing Personnel Signatures	Start Deviation Signatures	End Deviation Signatures		Printed Name / Tech Code	Signature	Signature	Date																																																																
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